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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,801

08/25/2003

Douglas A. Schein

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07/09/2008

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

NOTIFICATION DATE

DELIVERY MODE

07/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No. 10/646,801	Applicant(s) SCHEIN ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 24-35, 43 and 45-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 36-42 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 03/27/2008.

The examiner acknowledges the amendments made to the claims.

Claims 1-103 are pending in this application. Claims 24-35, 43, and 45-103 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2 and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by **Golyakhovsky** (U.S. Patent No. **4,800,879**).

Claims 1-2: Golyakhovsky discloses first **1** and second **2** portions that form a chamber **8** when brought together, a first fitting **11** on one of the first and the second portions, being in fluid communication with the chamber and having fluid flow substantially perpendicular to fluid flow through the hole, wherein the second portion has a hole (“cavity”) **9** in fluid communication with the chamber and adapted to receive a section of tissue and at least one sealing surface adapted to secure the section of tissue when the first and second portions are brought together (Figures 1-3).

Claims 9-16: Golyakhovsky discloses at least one fixing member **14b** and at least one compression strap **14a** arranged to wrap around at least part of the first portion and

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at least part of the second portion and to engage the fixing member so that the first and second portions are brought together, the compression strap extending from a sealing ring (the top part of first portion **1** that contacts tissue) and at least one engagement member or pre-positioning structure on one of the first and second portions and a complementary engagement member or complementary pre-positioning structure at a free end of the compression strap wherein the engagement member is arranged to engage the complementary engagement member (joined at **3**) while permitting relative movement of the first and second portions such that the first portion is substantially parallel to a second sealing surface on the second portions, also while the compression strap is wrapped around at least a part of the first portion and the second portion and engages the fixing member so that the first and second portions are brought together (Figures 1-3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Golyakhovsky** (U.S. Patent No. **4,800,879**).

Claim 3: Golyakhovsky does not expressly disclose that at least one of the first and second portions being formed of one of a transparent and a translucent material,

although Golyakhovsky discloses using plastic, and it would have been obvious to one of ordinary skill in the art at the time of invention to provide a transparent or translucent material increase visibility to ensure proper fluid flow.

5. Claims 4-8, 36-40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Golyakhovsky** (U.S. Patent No. **4,800,879**) in view of **Robinson** (U.S. Patent No. **6,726,651**).

Claims 4-8, 36-40, and 42: Golyakhovsky discloses the claimed device, but does not expressly disclose having the chamber being designed to collect gas separate from a fluid flow through the first fitting, the chamber and the hole, or having a second fitting formed on one of the first and second portions and being in fluid communication with the chamber that is formed when the first and second portions are brought together, the fluid flow being substantially perpendicular through the second fitting to the fluid flow through the hole, and the second fitting comprising at least one of a vent and a valve, the second fitting being connectable to a first fitting.

Robinson teaches a chamber **1220** designed to collect gas separate from a fluid flow through the first fitting, the chamber and the hole, or having a second fitting formed on one of the first and second portions and being in fluid communication with the chamber that is formed when the first and second portions are brought together, the fluid flow being substantially perpendicular through the second fitting to the fluid flow through the hole, and the second fitting comprising at least one of a vent and a valve **1240**, the second fitting being connectable to a first fitting (Figure 23). It would have

been obvious to one of ordinary skill in the art at the time of invention to provide a second fitting, as taught by Robinson, to Golyakhovsky in order to apply several instruments to the cannula while creating a fluid-tight seal.

6. Claims 17 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Golyakhovsky** (U.S. Patent No. **4,800,879**) in view of **Frampton** (U.S. Patent No. **3,538,915**).

Claims 17 and 41: Golyakhovsky discloses the claimed device, but does not expressly disclose a flange extending from an outer surface of the second portion.

Frampton teaches a flange **42** extending from an outer surface of the second portion (Figure 1). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a flange extending from the second portion outer surface, as taught by Frampton, to Golyakhovsky in order to increase surface area for contact with the organ and to maintain a sealed engagement.

7. Claims 18-23 and 44 rejected under 35 U.S.C. 103(a) as being unpatentable over **Golyakhovsky** (U.S. Patent No. **4,800,879**) in view of **Valley** (U.S. Patent No. **5,814,016**).

Claims 18-23, and 44: Golyakhovsky discloses the claimed device, but does not expressly disclose a sealing ring disposed between the top and bottom portions made of an elastomeric material, the ring having a complementary shape to the sealing surfaces.

Valley teaches a sealing ring **883** disposed between the top and bottom portions made of an elastomeric material, the ring having a complementary shape to the sealing surfaces (Figure 33, col. 45, lines 50-56). It would have been obvious to one of ordinary skill in the art at the time of invention to provide , as taught by Valley, to Golyakhovsky since it was well known in the art to provide an elastomeric sealing ring or gasket member in between two engaging members to avoid leaks.

Although the sealing surfaces do not have ribs, ridges, cuts, and protrusions, it would have been obvious to one of ordinary skill in the art to provide characteristics to increase the surface area of the ring to create a fluid-tight seal and avoid undesirable leaks.

Response to Arguments

8. Applicant's arguments filed 03/27/2008 have been fully considered but they are not persuasive.

9. Applicant generally argues that Golyakhovsky fails to disclose both the chamber and the hole of claim 1, wherein the hole is in fluid communication with the chamber, as well as a first fitting in fluid communication with the chamber, and a second fitting in fluid communication with at least one of the first fitting and the lumen. The examiner disagrees. As maintained above, the cavity 8 can be considered the chamber which is formed when the arms 1, 2 are brought together to occlude and seal a vessel, and the hole can be considered to be cavity 9, wherein the hole is in fluid communication with the chamber (see Figures 1-3), and the first fitting or valve 11 is in fluid communication

with the chamber 8 via a lumen, and the balloon 10 resides in the chamber and is in fluid communication with the valve 11. Robinson also teaches a chamber 1220 containing several fittings (Figure 23) in order to apply several instruments to the cannula while creating a fluid-tight seal.

10. The applicant also argues that Golyakhovsky fails to disclose a structure for allowing fluid flow between an external source and a blood vessel. However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., fluid flow between an external source and a blood vessel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/

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